

Application No. 09/979,569  
Attorney Docket No. PG3707USW

### REMARKS / ARGUMENTS

In the Official Action dated February 9, 2004, the examiner held:

- o The restriction applied to claims 1-25, 27-28, 37-62 and 70-78.
- o Claims 50, 52 and 53 were indefinite under 35 USC 112, 2<sup>nd</sup> ¶.
- o The claims were anticipated by US 3,565,132 to Lefort.
- o The claims were obvious over Lefort in view of the knowledge of one of ordinary skill, and in view of Dworak et al.

Claims 1-25, 27-28, 37-62 and 70-78 are currently pending. Claims 26, 29-36, 63-69, and 79 and 80 have been withdrawn under protest. The grounds for this withdrawal under protest will be addressed further herein.

**1. Claims 50, 52 and 53 Are Compliant with 35 USC 112, 2<sup>nd</sup> ¶**

The claims provided in applicants Response to Restriction Requirement filed 4/21/03 contained errors in the text of claims 1, 42, 50, 52 and 53 and in the status identifiers of many other claims. These errors were occurred through unintentional ministerial oversight. The claims as formally amended during the International Phase of the PCT, and in the First and Second Preliminary Amendments did not contain the objectionable language in Claims 50, 52 and 53, nor the punctuation errors present in claims 1 and 42. The corrected forms of these claims have been presented herein.

Further, the parenthetical status indicators for the pending claim set have been corrected to reflect the amendments made during PCT International Phase and in the Preliminary Amendments.

These corrections are made herein, but as the errors were not formally entered in prior amendments, the status indicators for claims 1, 42, 50, 52 and 53 are not indicated as "currently amended."

Application No. 09/979,569  
Attorney Docket No. PG3707USW

**2. Lefort (US 3,565,132) Does Not Anticipate As It Fails To Disclose Each Element Of Claims 1 or 42 or The Claims Dependent Thereon.**

LeFort discloses an apparatus for the continuous filling of bottles 15 with a powder. The apparatus has a rotary plate 14 on the upper surface of which are formed a plurality of radially-directed grooves 17 which, in use, feed powder to an associated bottle. At the radially outermost end of each groove there is an associated funnel 18 through which the powder in the groove is discharged through the plate into the associated bottle.

Also provided on the rotary plate are a plurality of doctor blades 10, one for each groove. Each doctor blade is disposed above an associated groove and as the plate rotates a series of cams and springs operate to sequentially pivot the doctor blade into the associated groove, move the doctor blade along the groove radially outwardly so that the powder in the groove is discharged through the associated funnel and to pivot the doctor blade back out of the groove. The position in the groove into which the doctor blade is pivoted determines the amount of powder discharged through the funnel into the bottle.

Statically mounted above the rotary plate is a powder reservoir 19 of oval shape. As the plate rotates underneath the powder reservoir the powder therein is gravity fed into the grooves. The doctor blades operate in the segment of rotation of the rotary plate proceeding filling.

The apparatus also has a rotary bottle feed table 25 from which empty bottles are loaded underneath the funnels as the rotary plate rotates. The bottles rotate with the rotary plate so as to be filled by the operation of the doctor blades. A rotary bottle takeoff table 26 unloads the filled bottles as the rotary plate rotates so that the bottle feed table can reload the apparatus.

*The present invention* concerns a method/apparatus of loading a container with a defined quantity of product. Claim 1 of the present application is the main method claim, while claim 42 is the main apparatus claim.

Application No. 09/979,569  
Attorney Docket No. PG3707USW

*Claim 1* requires that the method for loading the container with the defined quantity of product comprise *inter alia* the steps of (i) closing off a perforation in a perforated plate, and (ii) directing the product into the closed-off perforation by the action of a first leveller blade moving on a sweeping path relative to the perforated plate. The first leveller blade is required to be spaced from the plate and to present a forward acute angle to the sweeping path.

The Examiner appears to equate the action of the doctor blades 10 in LEFORT to that of the first leveller blade in the method claims of the present application. However, as a matter of simple language this is not the case. Clearly, the feature "first leveller blade" imparts a requirement that this feature have a levelling function. The doctor blades 10 in LEFORT serve no levelling function. They are simply means to scrape the powder out of the grooves 17 into the funnels 18. In this regard, it will be seen from FIGS 5-7 that the doctor blades 10 are drawn along the bottom of the grooves.

It can also be pointed out that when the doctor blades 10 scrape the powder from the grooves 17 into the funnels 18 the funnels are in open communication with the bottles 15 because this action fills the bottles with the powder (see FIG. 7, for example). Thus, the doctor blades 10 in LEFORT do not direct powder into a closed-off perforation in a perforated plate, as required in step (ii) of method claim 1 identified above.

For good measure, it can also be added that the stirrers 20 in the powder reservoir 19 of LEFORT do not equate to the "first leveller blade" of method claim 1 as they do not present a forward acute angle, as claimed.

In short, the Examiner's rejection of the pending method claims of this application is incorrect as LEFORT clearly does not disclose all of the method steps called for by these claims.

*Claim 42* requires that the apparatus comprise *inter alia* a perforate plate, a director for directing the product into a perforation in the plate which comprises a first leveller blade

Application No. 09/979,569  
Attorney Docket No. PG3707USW

movable on a sweeping path relative to the plate, and a transferor for transferring the contents of the perforation to the container. The first leveller blade is required to be spaced from the plate and to present a forward acute angle.

As mentioned above, the Examiner considers the doctor blades 10 in LEFORT to equate to the first leveller blade of apparatus claim 42, and thus that LEFORT discloses the "director" feature. However, this is incorrect since the doctor blades serve no levelling function *supra*.

Moreover, the doctor blades 10 do not direct product into a perforation, as required for the first leveller blade. If the rotary plate 16 is considered to be the perforated plate of apparatus claim 42, as contended by the Examiner, then this must mean that each funnel and associated groove is collectively held to be a "perforation". With this in mind, it is to be noted that the doctor blades 10 are only used after the powder is already in the "perforations". So, the doctor blades 10 do not equate to the "director" on this basis either.

The stirrers 20 in the powder reservoir 19 of LEFORT are also not equivalent to the "first leveller blade" of the apparatus claims for the same reasons outlined in relation to the method claims *supra*.

Consequently, the apparatus claims of this application are also novel over LEFORT.

**3. Claims 1-25, 27-28, 37-38, 4-62, 70-74 and 76-78 are not rendered Obviousness by LEFORT, or DWORAK (US 5,549,144)**

For the reasons mentioned above, LEFORT does not describe each element of claim 1 nor 42, and therefore cannot render obvious the claims dependent thereon.

Further though, the claimed designs in claims 10-13 assist in exerting a compressive force on the powder (Page 10, lines 1-6 of the specification), as this is not a function of

Application No. 09/979,569  
Attorney Docket No. PG3707USW

the scraper shown in LEFORT, there is no motivation to modify doctor blade (10) in LEFORT to the forms claimed in the claims 10-13.

As for the examiner's finding that claims 1-25, 27-28, 37-38, 4-62 and 70-74 and 76-78 are obvious in light of DWORAK in view of MORRIS, applicants respectfully disagree. Dworak discloses an apparatus for compressing powder into non-aerated pellets and then placing the pellets into pouches for sealing therein.

As shown in FIGS 1 and 2 of DWORAK, the apparatus has a rotary perforated plate 50 which sealingly rotates over a stationary plate 60. The stationary plate acts to keep the lower openings of the perforations 58 in the perforated plate closed except when the perforations rotate over a slot 64 in a segment of the stationary plate. In this way, powder can be loaded into the perforations when they rotate over the segment of the stationary plate which closes them and then ejected through the slot 64 into pouches 39 moving therebeneath.

The powder is deposited onto the upper surface of the perforated plate from a product feed belt. The powder is then manoeuvred by a series of plows 84, 86 and wipers 88 onto a predetermined recirculating path 20a which intersects the perforations so that the powder falls thereinto.

*MORRIS* discloses an apparatus for filling ammunition capshells 10 with a powder. In this apparatus, powder is fed onto a tray 3 from a chute 6 whereupon the powder is formed into a bed by a raking and levelling assembly 18 which comprises a comb 21 for raking the powder and a pair of doctor blades 21, 23 for levelling the powder bed. An array of hollow plungers 16, 17 are immersed in the powder bed to be filled with powder and then withdrawn and placed over the capshells where the powder is ejected from the plungers into the capshells.

The Examiner opines that the skilled person in the art, at the priority date of the present invention, would have routinely replaced the plows/wiper 84, 86, 88 in the DWORAK

Application No. 09/979,569  
Attorney Docket No. PG3707USW

apparatus with the leveller (doctor) blades 22, 23 disclosed in the MORRIS reference, and thus arrive at the present invention. The Examiner is mistaken.

To start with, there is no motivation provided in either DWORAK or MORRIS to make the modification proposed by the Examiner. The plows/wiper 84, 86, 88 in DWORAK have a completely different function from the leveller blades 22, 23 of MORRIS. The plows/wiper of DWORAK do not have a levelling function, like the leveller blades of MORRIS, but are mere means to steer the powder onto the recirculating path 20a. The skilled person in the art would therefore not make the substitution for this reason alone.

Moreover, it is to be noted from FIG 2 of DWORAK that the plows/wiper ensure that the powder is restricted to the recirculating path 20a. To achieve this the plows/wiper must extend to the surface of the rotary perforated plate 50. However, if the plows/wiper were replaced with the leveller blades 22, 23 of MORRIS, as suggested by the Examiner, this would not be the case since the leveller blades would be spaced above the rotary perforated plate. The result would be a lower portion of the powder passing underneath the leveller blades, and hence departing from the recirculating path, and an upper portion being spilled onto the recirculating path by the leveller blades. This would be completely contrary to the intended operation of the DWORAK apparatus and thus not contemplated by the skilled person in the art.

In short, the Examiner's reliance on the combination of DWORAK with MORRIS to impugn the inventive step of the present invention is untenable.

Accordingly, the claims of the present application are inventive over the prior art of record. Applicant's respectfully request that the rejection that claims 1-25, 27-28, 37-38, 40-62, 70-74 and 76-78 as obvious over DWORAK in view of MORRIS be withdrawn.

As claims 1 and 42 of the present invention is patentable, applicant's request that the all claims dependent on independent claims, including those dependent claims previously subjected to a restriction requirement be reinstated and allowed.

Application No. 09/979,569  
Attorney Docket No. PG3707USW

4. **The Examiner Misapplied the Controlling Law in Finding Lack of  
Unity of Invention and Requiring Election of Claims**

Claims are 26, 29-36, 63-69, 79 and 80 have been withdrawn in this Amendment under protest. This application is a national phase counterpart of a PCT International Application, filed in the US under 35 USC 371, to which unity of invention practice is applicable.

Claim 1 recites a method for loading a container. Claim 42 recites an apparatus sharing the special technical feature of claim 1, and being specially designed to carry out the process of claim 1. The examiner has correctly found that the independent claims, 1 and 42, of this application relate to a "single inventive concept of leveling a powder in order to provide measured filling of containers." Both claims 1 and 42 require that the leveller blade is spaced from the perforate plate, and presents a forward acute angle to the sweeping path.

Although the examiner makes this finding, he fails to state that this shared technical feature is also present in the withdrawn claims. The fact that the withdrawn claims also recite independently inventive subject matter is irrelevant. MPEP § 1850 A (page 1800-66 in the Feb 2003 revision) states:

*If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend from the independent claims. In particular, it does not matter if the dependent claim itself contains a further invention.... Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claims avoids the prior art and the combination claim includes all the features of features of the subcombination.*

Application No. 09/979,569  
Attorney Docket No. PG3707USW

Because each claim dependent from claims 1 and 42 share the special technical feature of the claims from which they depend, they fulfill the requirement of Unity of Invention. Hence Claims 1-78 should clearly be examined together, and failure to do so in contrary to Unity of Invention provisions.

The product-by-process claims, 79 and 80 should also be considered within the "inventive group" of claims, although they are a separate category from claims 1 and 42. According to MPEP §1850-C (page 1800-67 in the Feb 2003 revision):

*The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:*

*(C) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specially designed for carrying out the said process, it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed to carrying out a process if the contribution over the art of the apparatus or means corresponds to the contribution the process makes over the art.*

*Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and the claimed process. The words "specifically adapted" are not intended to imply that the product could not also be manufactured by a different process.*

For the reasons set forth, withdrawal of the restriction requirement, reinstatement of the withdrawn claims, and allowance of claims 1-80 is respectfully requested.



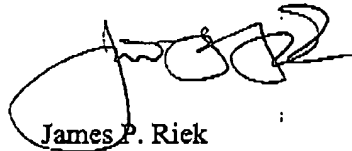
Application No. 09/979,569  
Attorney Docket No. PG3707USW

### CONCLUSION

In light of the corrections and explanatory statements made herein, all issues raised by the examiner to date have been addressed. Each claim has been shown to be novel and non-obvious over the cited art. As such, the claims are asserted to be in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,



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DPI's  
Tuesday 29<sup>th</sup> June 2004

1100 -1800hrs UK time, Conference Room 4  
1200 -1900hrs France time, XS meeting room  
0600 -1300hrs USA time, crown North11 13, 14, 15  
Chair: Dave Parkins

Dial in details

Conference dial-in number from UK:

+0800 9531289

Internal GSK Number

454 7777

Conference dial-in number (from outside UK):

+44 (0) 1452 558091

Conference Code:

626159#

UK TIME	PROJECT	LEADER
11:00 – 12:00	Dehydrated Lactose	Trevor Roche
12:00 – 12:30	Advair Diskus 50/50	Gavin Magee
12:30 – 12:45	Break	
12:45 – 13:45	Fluticasone Propionate Diskus	Rob Kitscha
13:45 – 14:30	Mk3 Filling Plans	Barry Sumby
14:30 – 15:00	Calcium Stearate	Marian Thomas
15:00 – 15:30	7-Day Drug Trial	Pallav Bulsara
15:30 – 16:00	Development of Diskus Foils Alternative Foils	Richard Walker
16:00 – 16:30	Titropium Diskus Progress Review	Michael Taylor
16:30 – 17:00	Use of Screens to Predict Stability	Dave Prime